

Message Text

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43

ORIGIN HEW-08

INFO OCT-01 EA-11 ISO-00 SCI-06 MED-03 RSC-01 /030 R

66610

DRAFTED BY: DHEW/FDA:LRSHELTON

APPROVED BY: SCI:AERICHMOND

DHEW/OIH:MACODDING

EA/J:WPIEZ

SCI/SA:MSBEAUBIEN

----- 048063

R 262050Z JUN 74

FM SECSTATE WASHDC

TO AMEMBASSY TOKYO

UNCLAS STATE 137657

E.O. 11652: N/A

TAGS: TBIO, JA

BJ: VOLUNTARY RECALL OF MEDICAL ADHESIVE

1. FDA ADVISES THAT DOW CORNING CORP., MIDLAND, MICHIGAN HAS REPORTED AN ERROR IN LABELING OF "DOW CORNING SILASTIC BRAND MEDICAL ADHESIVE SILICONE, TYPE A, CAT. NO. 891, NET WT. 2 OZ".
2. PRODUCT IS A MEDICAL ADHESIVE USED FOR BONDING DACRON TO ARTIFICIAL APPENDAGES; E.G., ARTIFICIAL NOSES, EARRS, ETC. PACKAGED IN CARTONS OF 6/2 OZ. TUBES EACH.
3. ONLY ONE LOT - HHQ327 INVOLVED. WAS MANUFACTURED ON 4/1/74, DISTRIBUTED BETWEEN 4/8/74 AND 5/16/74.
4. REASON FOR RECALL: PRINTING ERROR RESULTED IN LABEL OF SHIPPING CARTON AND OF TUBE CARTON BEARING STATEMENT "STERILE IN INNER PACKAGE". TUBE LABEL DOES NOT BEAR STATEMENT. THUS, PRODUCT ERRONEOUSLY LABELED SINCE TUBES ARE NOT STERILIZED, NOR HAS LOT BEEN TESTED TO ASSURE STERILITY. IT IS NOT INTENDED THAT THE PRODUCT BE SOLD AS STERILE.

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5. ONLY INTERNATIONAL CONSIGNEE:

FUJI POLYMER INDUSTRIES LTD.
571 AKEBACHO
YOKOHAMA, JAPAN

6. POST REQUESTED TO DETERMINE IF CONSIGNEE HAS BEEN
ADVISED TO RECALL TO USER LEVEL. SISCO

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CONSUMER PROTECTION, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 26 JUN 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE137657
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Document Unique ID: 00
Drafter: DHEW/FDA:LRSHELTON
Enclosure: n/a
Executive Order: N/A
Errors: N/A
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Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19740611/aaaaaiyd.tel
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Locator: TEXT ON-LINE, ON MICROFILM
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Original Classification: UNCLASSIFIED
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Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: martinjw
Review Comment: n/a
Review Content Flags:
Review Date: 21 OCT 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <21 OCT 2002 by PhilliR0>; APPROVED <13 JAN 2003 by martinjw>
Review Markings:

Declassified/Released
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30 JUN 2005

Review Media Identifier:
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